

**REMARKS**

In the present response, claims 1 and 6 are amended to even more clearly recite the present invention. Therefore, claims 1, 5, 6, 11, and 18 are pending in the application, with claim 18 being withdrawn from consideration.<sup>1</sup>

**Explanation, Support, and Entry of Amendment**

By this amendment, Applicants amend claim 1 to use “consisting essentially of” transition language and to delete recitation of the database. Claim 1 is also amended to recite “[only normal] reference cells . . . [tumor] specimen cell . . . .” See, e.g., present application at page 7, lines 21-22, for support for reciting reference and specimen cells. Claim 1 is further amended to delete “from a subject . . . .” See, e.g., present application at page 7, lines 21-28, for support for this deletion.

Claim 6 is amended to recite “a peak analysis [techniques] technique” for grammatical reasons. Therefore, this amendment does not create any estoppel. In other words, the protein data processing unit of claim 6 may use one or more peak analysis techniques.

Accordingly, no new matter has been added by the amendments.

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<sup>1</sup> It is not completely clear whether claim 11 is withdrawn from consideration. Although the Examiner indicates that claim 11 is withdrawn from consideration, the Examiner rejects claim 11 under 35 U.S.C. §§ 102(b) and 112. Office Action at 2-3. Since the Examiner provided arguments to support withdrawal of claim 18, but did not provide any arguments to support withdrawal of claim 11, Applicants expect that the Examiner did not intend to withdraw claim 11.

Applicants respectfully request that this amendment be entered. Applicants respectfully submit that the present amendment places the application in condition for allowance, as discussed in more detail below. Applicants also submit that the present amendment would place the application in better form for appeal, should the Office continue to dispute the patentability of the pending claims.

### **Response to Election of Species Requirement**

Claim 18 has been withdrawn from consideration as being directed to non-elected subject matter. The Examiner asserts that this claim is independent or distinct from the invention originally claimed. In response, Applicants note that claim 18 has been amended to depend from independent claim 1. Therefore, Applicants submit that this dependent claim should be considered.

In view of the above, Applicants request withdrawal of the Election/Restriction requirement.

### **Response to § 112 Rejection**

Claim 11 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for reciting “comprehensive protein profile . . . .” Office Action at 2.

In contrast with the assertions of the Examiner, Applicants respectfully submit that a skilled artisan would understand the meaning of “comprehensive protein profile . . . .” In particular, in the context of the present application, a skilled artisan would understand this term to mean a complete data set representing the cell expression protein profile from the mass spectra of the recited protein content. See, e.g., independent claim 1 and Abstract of the Disclosure.

In view of the above, Applicants respectfully request withdrawal of this ground of rejection.

### **Response to § 102(b) Rejection**

Claims 1, 5, 6, and 11 are rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,538,897 to YATES et al. The Office asserts that YATES “teaches the use of mass spectrometry fragmentation patterns of peptides to identify amino acid sequences in databases.” Office Action at 3 (emphasis added). “A protein sequence database or a nucleotide sequence database is used to predict one or more fragment spectra for comparison with the fragment spectrum . . . .” Id. (emphasis added)

Applicants respectfully traverse this rejection for the reasons of record and those that follow.

Applicants respectfully submit that YATES fails to disclose or suggest the recited protein profiling system for identifying a protein biomarker characteristic of at least one specimen cell, consisting essentially of: a protein fractionation unit . . .; a mass spectrometer . . .; and a protein data processing unit . . . . As noted by the Examiner, YATES teaches the use of a database. YATES fails to disclose or suggest that its database may be omitted. To the contrary, Applicants submit that a skilled artisan would understand that the database is an important aspect of the invention of YATES. See YATES at, e.g., Title of Invention, independent claims 1 and 18, Abstract, and col. 1, lines 6-9. Therefore, YATES fails to disclose or suggest the recited protein profiling system for identifying a protein biomarker characteristic of a specimen cell, consisting essentially of: a protein fractionation unit . . .; a mass spectrometer . . .; and a protein data processing unit . . . .

In this regard, YATES discloses comparing data from a collected sample with information in a database, e.g., in order to identify anomalies. YATES discloses the use of known databases, (col. 3, line 53-67), and YATES discloses that its invention may be used in diagnostic applications, (col. 17, lines 62-64).

In contrast to YATES, the present invention does not require a database, but rather relies on a comparison between samples. Thus, in one embodiment of the present invention, one sample from a patient is compared with another sample from the same

patient to see whether there is differential expression. By comparing the protein spectrum of reference tissue to a protein spectrum of specimen tissue from the same patient, differences in the expression of specific proteins can be detected. See, e.g., present application at page 7, lines 22-24. Alternatively, a sample from one patient can be compared with a sample from another patient. No database or library of protein profiles is therefore necessary with the present invention.

In view of the above, Applicants respectfully request withdrawal of this ground of rejection.

### **CONCLUSION**

In view of the foregoing amendments and remarks, it is respectfully submitted that the application is in condition for allowance. If the Examiner believes that any additional changes would place the application in better condition for allowance, the Examiner is invited to contact the undersigned attorney, Steven J. Helmer, at the telephone number listed below. Favorable consideration and prompt allowance are earnestly solicited.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this, concurrent and future replies, including extension of time fees, to Deposit Account 16-0607 and please credit any excess fees to such deposit account.

Respectfully submitted,  
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